DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 October 2008 has been entered.

Response to Arguments

2. Applicant's arguments filed 3 October 2008 have been fully considered but they are not persuasive.

3. Applicant's arguments with respect to the claimed protease inhibitor have been considered but are moot in view of the new ground(s) of rejection.

4. In response to the applicant's argument with respect to the concentration of the protease inhibitor, it is noted that the suggestion by Roe that the lotion should be applied in a concentration that provides suitable therapeutic benefit while not saturating the topsheet provides motivation to one of ordinary skill in the art to determine a workable range of concentration for the composition. The claimed range, ranging from a very small amount to a significant amount of composition by weight of the article, would be obvious because it provides a reasonable expectation of success for application of the composition in an amount that serves the purpose disclosed by Roe.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 31, 32, 36, 42-44, 46, 48, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) in view of McAtee et al. (5,607,980).

7. With respect to claims 31, 32, 36, 42 and 44, Roe discloses all aspects of the claimed invention with the exception of the protease inhibitor being hexamidine and present in the amount of 0.0001-5% by weight. Roe discloses a disposable wearable article comprising a liquid permeable topsheet 520, a liquid impervious backsheet 530, and an absorbent core 540. The topsheet comprises a delivery system in the form of a lotion, as disclosed in column 3, lines 3-5. The lotion includes an antibacterial, as disclosed in column 23, lines 24-31.

8. McAtee teaches the use of an antibacterial protease inhibitor, hexamidine, in a lotion composition, as described in column 11, line 61, and column 12, line 1. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the lotion of Roe with hexamidine, as taught by McAtee, to yield the predictable result of providing the lotion with antimicrobial activity.

9. The lotion of Roe is applied to the topsheet in an amount that will impart the desired therapeutic benefits of the lotion without saturating the topsheet, as disclosed in column 24, lines 1-12. It would therefore have been obvious to one of ordinary skill in the art at the time of invention to apply the lotion in an amount such that the protease inhibitor would be present in the article in a range of about 0.0001% to about 5% by

weight because there would have been a reasonable expectation of success that such an amount would provide a therapeutic benefit without requiring so much lotion that the topsheet would be saturated.

10. The IC_{50} is defined in the instant specification on page 7 as being dependant on the concentration of protease inhibitor and the rate of substrate cleavage of the protease inhibitor. The rate of substrate cleavage is dependent on the individual protease inhibitor, and hexamidine is disclosed in the specification as being a suitable protease inhibitor. Therefore, jexamidine, when present in the claimed concentration, inherently has an IC_{50} of about 500 μM or less, no more than 100 μM, and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease.

11. With respect to claim 43, the lotion is transferable to the skin of a wearer, as disclosed in column 25, lines 25-27.

12. With respect to claim 46, the deliver system contains the protease inhibitor as molecules, or particles, as disclosed by McAtee in column 10, lines 47-49.

13. With respect to claim 48, the lotion is applied to the wearer-contacting surface of the topsheet, as disclosed in column 25, lines 25-27.

14. With respect to claims 52 and 53, the lotion is applied in a plurality of stripes with a region of the topsheet not containing lotion, as shown in figure 2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. A./
Examiner, Art Unit 3761
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